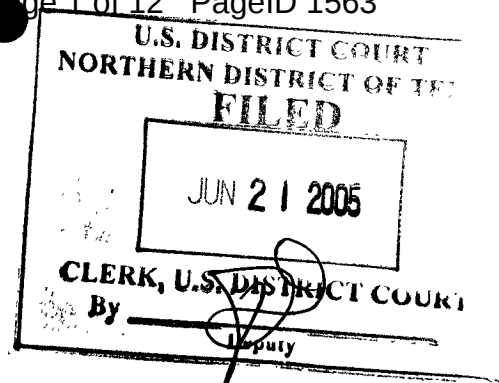


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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION



LASANDRA MADDEN Individually and on §  
Behalf of LABREA WILLIAMS, a minor child, §

Plaintiffs, §

vs. §

ORIGINAL §

CIVIL ACTION NO. 3:03-CV-0167-BD §

WYETH d/b/a WYETH, INC., f/k/a §  
AMERICAN HOME PRODUCTS §  
CORPORATION; WYETH CONSUMER §  
HEALTHCARE, an unincorporated §  
Division of WYETH, f/k/a WHITEHALL- §  
ROBINS HEALTHCARE; AND §  
WHITEHALL LABORATORIES, INC., §

Defendants. §

**PLAINTIFFS' REPLY TO DEFENDANT'S RESPONSE  
TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT**

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**I. Plaintiffs are not improperly using partial motion for summary judgment.**

**A. Defendant's "brief disguised as a motion" should be stricken.** Defendant has filed a nine page "motion," which contains several pages of obvious argument, including objections, in violation of LR 56.4. Therefore, it must be stricken in its entirety, including the objections.

**B. Defendant's "piecemealing" argument is misdirected.** If the court grants summary judgment on negligent/strict liability failure to warn, and on general and specific causation, plaintiffs are entitled to a partial summary judgment on liability, and bifurcation of liability and damages is clearly proper. *See, e.g., Sanford, et al. v. Johns-Manville Sales Corp*, 923 F.2d 1142, 1146 n.7 (5<sup>th</sup> Cir. 1991). Additionally, FRCP 42(b) "provides that a court may bifurcate any claim or *separate issue* in a trial in order to promote convenience or to avoid prejudice." *Holland v. Harmon*, 1999 U.S. Dist. LEXIS 1081, \*2 (N.D. Tex. 1999) (Judge Fitzwater) (emphasis added) (citing *Rosales v. Honda Motor Co.*, 726 F.2d 259, 260 (5th Cir. 1984)).

**II. Plaintiffs are entitled to summary judgment on the failure to warn issue.**

**A. Reply to defendant's statement of genuine issues relevant to the warning claim.**

**1. OTC labeling requirements:** Defendant cites hearsay evidence in the form of FDA-conducted studies and studies allegedly conducted by Wyeth, which were apparently relied on by its retained expert Waymack, yet not produced in its Rule 26 disclosure. Thus, these studies should be stricken. Moreover, Waymack offered no opinions about such studies in his original report, and should therefore be stricken for that reason as well.<sup>1</sup>

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<sup>1</sup> *See* Def.'s Rule 26(a)(2) Expert Disclosures, served on or about Feb. 4, 2005. Defendant has argued on pp. 23–25 of its Response that plaintiffs are not entitled to rely on the opinions of Dr. Neuman, a treating doctor, because they are untimely. Although there is a clear distinction between Dr. Waymack, a retained expert, and Dr. Neuman, a treater, defendant should certainly not be able to inject new arguments, based on studies not previously disclosed, from a retained expert like Waymack. Further, accepting that OTC labels must be understood by the ordinary individual, clearly a warning to stop the drug immediately and call the doctor if a rash or blisters develops would be so understandable, and apparently the FDA agrees. *See* n.9, *infra*.

**2. Reporting of articles:** Defendant's contention that "the FDA only requires that pertinent and relevant literature be submitted" is false. It cites 21 CFR § 314.80, but fails to cite § 314.81, which provides that defendant is required to file annually "significant new information from the previous year that *might affect* the safety, effectiveness, or labeling of the drug product" (emphasis added). This includes all scientific literature plaintiffs identified because it all shows the increased risk of SJS and TEN, life-threatening skin reactions. Defendant again cites its retained expert Waymack for new opinions regarding FDA reporting requirements not disclosed in its R. 26 disclosure. Thus, Waymack's opinions regarding FDA reporting requirements should be stricken.<sup>2</sup>

**3. Review of literature at Wyeth:** Defendant falsely claims that a team, not an individual, had responsibility for reviewing the scientific literature and fulfilling Wyeth's annual reporting requirements, and thus disputes plaintiffs' claim that no one had this responsibility. However, Wyeth's Sr. Director for Product Safety, Dr. Anthony Ewell, whose department had responsibility for this activity, testified as follows:

Q. (by Mr. Barber): All right. So, well, maybe I misunderstood you then. Are you saying there was more than one person assigned that task (of researching the literature)?

A. *I didn't say that either....*

Q. If there wasn't one person responsible for it and there wasn't more than one person responsible for it Doctor, then the clear implication is that nobody was responsible for it. Now why is that incorrect? ....

A. *I don't know.* (emphasis added).

(Ewell dep., Att. 8, App. 176, to Pls. ' Mot. for Partial Summary J.).<sup>3</sup>

**4. SJS and the label for Children's Advil in Europe:** Defendant, relying on the testimony of Roger Berlin, its President of Global Scientific Affairs, falsely claims that foreign

<sup>2</sup> These include his opinions at *Def.'s App.* 326, ¶¶ 7, 8, 9, and 10. (All references to "*Def.'s App.*" are to the page numbers of the *Appendix* accompanying Defendant's Response).

<sup>3</sup> It was only after coaching by defense counsel, and on redirect, that Ewell attempted to testify that it was a team effort. (See *Def.'s App.* 467-68).

labels were not distributed with the product to the consumer. However, Berlin admitted he based his knowledge “on what people told me.” (Berlin dep. 292, *Def.’s App.* 547). He also stated “Well, I don’t prepare the PILs (Patient Information Leaflets), and—and as I testified earlier, that is *to the best of my understanding* this change was made solely to the SMPC.” (*Id.* at 294, *App.* 548) (emphasis added). His testimony is thus hearsay and should be excluded for that reason.

It is undisputed that the PIL is the brochure that is distributed with the product to the patient (*id.*), and although plaintiffs requested and defendant agreed to produce all foreign labels and warnings, the PILs had not been produced as of the date of Berlin’s deposition, and were not produced until approximately four months later, after the dispositive motion deadline had passed.<sup>4</sup> Plaintiffs object to Berlin’s testimony as hearsay, and they further object on the basis that defendant failed to timely produce discoverable labeling documents that it had agreed and this court had earlier ordered produced in Dec. 2003, and is now attempting to rely on plaintiffs’ failure to adduce this very proof.<sup>5</sup>

Additionally, when the PIL’s were finally produced by defendant, the French PIL clearly shows that the SJS warning was contained in the PIL distributed with the product to the consumer. No explanation was ever provided for why these labels were not produced sooner, nor did Mr. Cohen ever apologize for his inaccurate representation about this fact. This document, which is Att. 16 to Plaintiffs’ Response to Defendant’s Motion for Summary

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<sup>4</sup> Pretrial Discovery Order, Dec. 9, 2003, p. 3, ¶ (B). Mr. Cohen stated at Dr. Berlin’s deposition, at 295 (*Def.’s App.* 548), that “To the best of my knowledge, we have produced all those labels to you. If we have overlooked the PIL, I apologize, and I will get that to you immediately.” However, no PIL’s were produced until Apr. 22, 2005, about 5 days after the summary judgment deadline. (*See Att. 1—Sims’ ltr, 4/22/05, App.* 1–23). The French PIL is Att. 16 to Pls.’ Resp. to Def.’s Mot. for Summary J., filed June 2, 2005, and it is incorporated herein by reference. It was not filed sooner because defendant deliberately withheld it until after the dispositive motion deadline.

<sup>5</sup> *See* Pretrial Discovery Order dated Dec. 9, 2003, p. 3, ¶ (B), where the court noted that “the defendant has agreed to give the plaintiffs all foreign labeling and foreign warnings.” Defendant deliberately waited until after the dispositive motion deadline to comply with this order. As discussed *infra*, p. 7, defendant also attacks plaintiffs’ proof of foreign labeling for failure to disclose the very PIL labels that it deliberately withheld until after the dispositive motion deadline had passed.

Judgment, clearly shows that the SJS warning was included in the Patient Information Leaflet (PIL), and is incorporated by reference herein.<sup>6</sup> Thus Berlin either committed deliberate perjury, or simply did not know what he was talking about.

**5. Failure to report two arguable SJS cases in the CAMP study:** Defendant's "evidence" on this point is the testimony of its retained expert Waymack, who had nothing to do with the CAMP study and is not a Wyeth official with any firsthand knowledge of whether these cases were reported or not. No basis for his opinions about the CAMP study is shown in either his declaration or his deposition. His testimony is thus hearsay, and is objected to for that reason. Secondly, he fails to point out that these two SJS cases were not included in the reports of serious ADE's that were filed with the FDA arising out of the CAMP study.<sup>7</sup> Also, he fails to acknowledge that Wyeth never at any time questioned the causal relationship of these cases to ibuprofen, according to its Sr. Director of Medical Affairs at that time, Sandy Furey.<sup>8</sup>

**6. FDA's recognition that Wyeth failed to report:** As will be discussed *infra*, the FDA has today (June 15, 2005) ordered Wyeth and all OTC NSAID manufacturers to revise the "allergy alert for these products . . . to include a warning for aspirin sensitive individuals and a

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<sup>6</sup> As noted in Pls.' Resp. to Def.'s Mot., n.34, this label provides: ". . . In case of apparition of cutaneous or mucous signs which look like burns (redness of the skin associated to bullous, blister or ulceration) DISCONTINUE TREATMENT AND IMMEDIATELY CONTACT A DOCTOR OR AN EMERGENCY MEDICAL SERVICE." (emphasis in original). This is very similar to the warning now ordered to be implemented by the FDA. (See n.9, *infra*). Plaintiffs realize that the court has ordered that no additional summary judgment evidence be filed by either party. However, this is a case where defense counsel stated on the record that all such labels had been produced, and then after the summary judgment deadline had passed, produced additional labels; and now is attacking plaintiffs' summary judgment proof because they didn't attach the labels. This should be justification for this incorporation by reference, and plaintiffs respectfully request the court to consider it.

<sup>7</sup> This was confirmed by the testimony of Wyeth Sr. Director of Medical Affairs, Dr. Sandy Furey, and Ex. 6 to his deposition, but this testimony would be additional summary judgment evidence and cannot be filed by plaintiffs. (Dep. of Sandy Furey (Wyeth Sr. Dir. of Med. Affairs 1991-95) at 131, 132, 138, 139). Furey testified that he didn't know why the two SJS cases were not included in the serious cases reported to the FDA, which were attached to his deposition as Ex. 6.

<sup>8</sup> Furey testified that he didn't know whether Wyeth ever questioned the causality of these cases, and he was the Wyeth official who submitted the serious ADE reports arising out of CAMP to the FDA. (See Furey dep., Att. 16, App. 248 to Pls.' Mot. for Partial Summary J.).

*description of early symptoms associated with Stevens-Johnson Syndrome (SJS)."*<sup>9</sup> (emphasis added). As the FDA stated on Apr. 7, 2005,<sup>10</sup> "These actions [asking manufacturers of NSAIDs, including Wyeth, to include a warning on OTC products about potential skin reactions] are *based on the available scientific data, including data accumulated since the drugs were approved.*" (emphasis added). Since Rx Children's Advil was first approved in 1989, this is clear evidence that the proof had been in the literature since that time. Plaintiffs have clearly shown that defendants did not report any of the literature that this action is obviously based on.

***B. Reply to defendant's claim that plaintiffs' statement of facts regarding failure to warn is inaccurate.***

**1. Plaintiff's contention that defendant failed to submit required medical literature to the FDA.**

***i. Defendant's claim that it must only file "pertinent and relevant" literature is false.***

First, plaintiffs have already shown above that defendant is required to submit in its Annual Reports "significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product," and it failed to do so. 21 CFR § 314.81(b)(2)(i).<sup>11</sup> Defendant's claim that it is only required to file "pertinent and relevant" literature is not supported by any language in the regulations. Second, defendant again relies on an opinion of its

<sup>9</sup> See [www.fda.gov/cder/drug/infopage/COX2/NSAIDotcSuppLtr.pdf](http://www.fda.gov/cder/drug/infopage/COX2/NSAIDotcSuppLtr.pdf). (Att. 2, App. 24-31). Contrary to defendant's assertion, government website postings fall within the official records exception to the Hearsay Rule. See *EEOC v. Dupont*, 2004 U.S. Dist. LEXIS 20753, \*3-5 (E.D. La. 2004) (citing Fed. R. Evid. 803(8)). Plaintiffs further ask that the Court judicially notice this action by the FDA, pursuant to Fed. R. Evid. 201, and allow this additional summary judgment evidence since it did not exist at the time of the dispositive motion deadline. See *In re Wellbutrin Antitrust Litigation*, 281 F.Supp.2d 751, 755 n.2 (E.D. Pa. 2003) (court judicially noticed an FDA report published on an official government website).

<sup>10</sup> See App. 1 (Att. 1) of Pls.' Mot. for Partial Summary J.

<sup>11</sup> See also 21 C.F.R. § 314.50(d)(5)(iv), which required Wyeth to include in the Children's Advil NDA "any other data or information relevant to an evaluation of the safety and effectiveness of the drug." (emphasis added).

retained expert Waymack that was not in its Rule 26 disclosure. Therefore, it should be stricken and not considered for any purpose.<sup>12</sup>

***ii. Defendant's claim that it filed the literature, or if not, it wasn't required to, is false.***

Defendant's "proof" on this point is in the form of a "declaration" from Dr. Ashraf, who now claims to have filed the literature she previously testified was not included in Wyeth's Annual Reports (which are required to comply with 21 CFR § 314.81); or if she didn't, that it's not required to be filed. This "declaration" is devoid of credibility as a matter of law, first because it is in conflict with her sworn deposition testimony, and second, because she offers no specific regulatory language supporting her opinions.

She first argues that it's in compliance with FDA regulations to file scientific literature discussing the safety of ibuprofen only with the Adult Advil NDA and not the Children's Advil NDA, even if they contain the same ingredient, which is hearsay and a legal opinion outside her competence—and she cites *not one whit of regulatory support for this argument!*<sup>13</sup> Second, she argues that review articles, etc., are not required to be filed, again without citing any regulatory support for this position. This testimony is also contrary to that of Dr. Ewell, who testified that *all literature* dealing with any single ingredient ibuprofen product must be reported.<sup>14</sup> And again,

<sup>12</sup> Defendant also falsely claims that ADE reports from the FDA AERS database and the World Health Organization (WHO) are inadmissible hearsay. They may be hearsay, but they are admissible when offered to prove that the defendant had knowledge or notice of the risk. See *Mauldin v. Upjohn Co.*, 697 F.2d 644, 648 & n.6 (5<sup>th</sup> Cir.1983, cert. denied, 464 U.S. 848 (1983)). Also, medical articles are admissible to show knowledge or notice of the risk of SJS and TEN associated with ibuprofen. Cf., *Kershaw v. Sterling Drug, Inc.*, 415 F.2d 1009, 1011 (5<sup>th</sup> Cir.1969).

<sup>13</sup> Also, any reference by defendant to the Adult Advil NDA should be excluded, because defense counsel has stated since Sept. 22, 2003, that "We will not voluntarily produce ADE's and information about Adult Advil". (Sims ltr, 9/22/03). Thus, defendant should not be allowed to benefit by reference to the Adult NDAs. And it should be noted that even if Wyeth did file them under the Adult Advil NDA, ***this still clearly shows they had notice of each article, and thus were aware of the growing evidence of the association between SJS/TEN and ibuprofen!*** Dr. Ewell also confirmed that there was no regulatory basis for Wyeth's policy of not filing reports of adverse reactions associated with ibuprofen to the Children's Advil NDA if they involved adults. (Ewell dep., App. 184 (Att. 8) of *Pls' Mot.*).

<sup>14</sup> Ewell also confirmed that no scientific literature was reported between 1996 and 2000, included the 1995 Mockenhaupt article reporting a 4.5 multivariate crude RR between ibuprofen and SJS/TEN. See *id.*, App.181–83.

Wyeth trots out Dr. Waymack, its all-purpose retained expert, who again expresses opinions that are totally conclusory, not included in defendant's Rule 26 Disclosure, and plaintiffs so object.<sup>15</sup>

***C. Plaintiffs' foreign labeling claims do support summary judgment.***

Defendant first argues that because plaintiffs did not offer as summary judgment evidence any PILs that were distributed with Children's Advil in Europe, allegedly in violation of the Best Evidence Rule, they didn't prove that defendant warned about SJS in Europe but not in the U.S. However, as shown above, at n.4 & n.5, defendants deliberately withheld producing PILs until after the summary judgment deadline. Therefore, it would obviously be unfair for them to capitalize on that point with their "Best Evidence" objection.

Further, contrary to defendant's implication, Dr. Blume's testimony in her Affidavit is competent summary judgment proof that defendant warned of SJS in the label distributed with consumers of Advil products in Europe, and *defendant never denies by any witness that SJS was warned about on the label of their OTC product in Europe!* (See Blume Aff., App. 1104-07 (Att. 29) of Pls.' Mot.).<sup>16</sup> Rather, defendant simply criticizes plaintiffs' proof for technical best evidence reasons. Their "evidence," if any, is not probative and is inadmissible on this point.

**1. Foreign labeling is clearly relevant and admissible to show knowledge or notice of the danger.**

All of the cases cited by defendant in support of its argument that foreign labels are irrelevant are cases holding that the *foreign legal standard* is irrelevant, not that the label is not admissible to prove knowledge or notice. This includes *Deviner v. Electrolux* and the other

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<sup>15</sup> Waymack states that the conclusion that "Wyeth provided the FDA with all required reports and documents." (Def.'s App. 327, ¶ 12). He does not state that he has reviewed all of Wyeth's Annual and Periodic Reports, or what he bases this sweeping conclusion on. Nor, for that matter, does he identify the basis for this opinion at all. This opinion is the rankest form of sweeping conclusion without any basis stated in fact. Plaintiffs also object to Waymack's legal conclusions that Wyeth did not violate any federal regulations. (Def.'s App. 404).

<sup>16</sup> Also, it may not be clear from Blume's Affidavit, but plaintiffs *did attach* a copy of the German PIL that Dr. Blume obtained for the German Children's Advil product called Spalt, and it does show that defendant warned German consumers directly about SJS. (Pls.' Mot. for Partial Summary J., Att.19, App. 472).



cases cited on pp. 11–12 of its Response brief. Clearly, under FRE 401, evidence “having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable” is admissible.<sup>17</sup> In a failure to warn case, plaintiffs must prove that Wyeth had actual or constructive knowledge of the risk of SJS and TEN associated with ibuprofen to recover.<sup>18</sup> Clearly where, as here, the foreign labels are offered to show knowledge or notice of the risk, they are admissible. The same is true of the report of Dr. Julien.<sup>19</sup>

***D. The FDA’s action this week requiring an SJS warning on OTC ibuprofen products proves conclusively that defendant’s warning is inadequate.***

As noted above at n.9, on June 15, 2005 the FDA issued a Supplemental Labeling Request to all OTC NSAID manufacturers, including Wyeth, requiring all manufacturers of OTC ibuprofen products, including Children’s Advil, to revise their product label “***to include . . . a description of early symptoms associated with Stevens-Johnson Syndrome (SJS).***”<sup>20</sup> (emphasis added). The FDA states that “. . . we believe that labeling changes are warranted . . .” and “we request that you revise the labeling for all of your over-the-counter (OTC) products that contain any of the following ingredients: ibuprofen . . .” (*App.* 24).

This action by the FDA clearly refutes defendant’s claim that “the FDA has taken no action.” (*Def.’s Resp. Brief* at 14). Defendant has claimed all along in this case that the FDA had the authority to determine the contents of its OTC labeling, and the FDA has now stated that

<sup>17</sup> Additionally, 21 C.F.R. 314.80(b) provides that the NDA holder (Wyeth) “shall promptly review ***all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic . . .***” (emphasis added). Thus, if foreign labeling changes adding SJS are made, defendant clearly has a duty to report these changes to the FDA, because the implications for the safety of the drug in the U.S. are obvious.

<sup>18</sup> See, e.g., *Shoptite Foods, Inc. v. Upjohn Co.*, 619 S.W.2d 574, 578–80 (Tex. App.—Amarillo 1981, writ ref’d n.r.e.). Defendant admits that this is an element of plaintiffs’ claim. (*Def.’s Resp. Brief* at 14).

<sup>19</sup> Defendant also argues that Dr. Julien’s report related to French labeling is not “verified.” However, it is not offered for the truth of the contents, but again to show notice to the defendant of the risk. Further, any document produced in the discovery process should be presumed authentic, and it is further authenticated by the Affidavit of James C. Barber, Att. A to Pls.’ Mot. It should be noted that plaintiffs attempted to depose Dr. Julien while in Paris, and went through the Treaty procedure required, but Julien claimed to be “sick,” and did not attend his deposition.

<sup>20</sup> Plaintiffs have attached a copy of this Supplemental Labeling Request as Att. 2, *App.* 24–31 hereto, and request the Court to take judicial notice of this action by the FDA, under Fed. R. Evid. 201.

it is inadequate, “based on the available scientific data, including data accumulated since the drugs were approved.” (FDA notice of Apr. 7, 2005, discussed *supra*, p. 5).

Further, plaintiffs have shown in their Response to Defendant’s Motion for Summary Judgment that defendant’s own expert, Dr. Roujeau, reported as early as 1984 that “NSAIDs were now the main cause of drug-induced TEN in the French study” (Dep. of Roujeau at 105, *App.* 29 of Def.’s Resp.). Roujeau and/or his colleagues reported the same about NSAIDs including ibuprofen in 1987, twice in 1990, and in 1995. Then, in 2003, they found a five-fold increase in the relative risk of SJS and TEN associated with ibuprofen.<sup>21</sup> Against the backdrop of this overwhelming evidence in the literature, defendant’s suggestion that the FDA’s action is based on “new data” is ludicrous. (*Def.’s Resp. Brief* at 14).<sup>22</sup>

### **III. Plaintiffs are entitled to partial summary judgment on causation.**

#### ***A. Defendant’s own expert has admitted general causation, and plaintiffs’ experts have proved it conclusively.***

Defendant’s continued assertion that plaintiffs have not proved general causation is disingenuous at best and bad faith at worst. ***Defendant’s own expert Stern has admitted general causation, and this admission, together with the literature and epidemiologic evidence, is determinative of this issue!*** Stern, self-proclaimed and proclaimed by defendant to be one of the country’s leading experts on SJS and TEN, has given the following testimony, as discussed in Plaintiffs’ Response to Defendant’s Motion for Summary Judgment, pp. 6–7:

***Q. And do you agree that there is evidence in the 2003 SCAR study that ibuprofen can cause TEN?***

<sup>21</sup> See Roujeau dep., *supra*, *Def.’s App.* 29–30; *Pls.’ Resp. to Def.’s Mot. for Summary J.*, p. 6, filed June 2, 2005.

<sup>22</sup> That everyone in the field knew of this risk as early as the eighties is further supported by defense expert Stern’s admission that prior to the 1995 SCAR study, in the early eighties, most researchers agreed that all NSAIDs caused SJS and TEN, including ibuprofen. (*Def.’s App.* #2, 147–50). The irony is that defendant still claims that there is no causal relationship between ibuprofen and SJS and TEN, even though the FDA has now ordered them to warn about that very risk. This development shows that this corporate defendant is acting maliciously and without regard to the truth, ordinary care, or common sense, and is motivated only by greed!

A. *Yes*. It think that this is one of the areas that Dr. Roujeau and I are not in complete agreement about. *I think it is more likely than not...that ibuprofen is a possible cause of SJS and TEN...*

....

Q. *Do you agree that it (ibuprofen) is a cause of SJS and TEN albeit rare in your opinion?*

A. *Yes*.

This testimony, in addition to the testimony of plaintiffs' experts and the overwhelming evidence in the literature, shows that general causation was thought by all experts in the field to be proved even in the early eighties, by the admission of defendant's own expert, and that it is certainly proved to his satisfaction now. And apparently the FDA thinks so, or they wouldn't have ordered the defendant to add an SJS warning to their label.<sup>23</sup>

***B. Individual causation is also proven conclusively.***

Plaintiffs have shown that they are entitled to summary judgment on this issue in their Motion papers, and their Response to Defendants' Motion. As plaintiffs' counsel predicted, defendant is attacking the legal competency of the Lymphocyte Toxicity Assay test performed on this child, claiming it is hearsay.<sup>24</sup> Plaintiffs believe that the records of this test are properly proved up as business records, but the court has previously stated that if it felt that the hearsay objection was valid plaintiffs would be given the opportunity to take the deposition of Dr. Manuela Neuman, who performed the test.<sup>25</sup>

Dated this 21st day of June, 2005.

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<sup>23</sup> It is also clear that Dr. Roujeau's position, based on the 2003 SCAR study (Mockenhaupt, *et al.*), is that the Mockenhaupt study, finding a 5.3 RR association between ibuprofen and SJS and TEN, is the "best available evidence." (Roujeau dep. at 113, *Pls.' Resp. App.* 14). Nor can defendant rely on the unpublished "new study" cited on pg. 22 of its brief, because it has never been produced, and Mr. Cohen has stated in a recent letter that "...Dr. Roujeau stated [on his deposition] that his opinions pertaining to Labrea Williams have nothing to do with the recent study in which he was involved." Further, it is undisputed that this "new study" was not timely disclosed under R.26, and any inference based on it must be stricken.

<sup>24</sup> This test result is attached to *Pls.' Mot.* as Att. 24, *App.* 536-48, and to *Pls.' Resp.* as Att. 12, *App.* 328-50. Additionally, the test is now supported by the Affidavit of Dr. Neuman, Att. 19, *App.* 394-402, of *Pls.' Resp.*, which is incorporated herein by reference.

<sup>25</sup> The deposition will not be necessary if the Affidavit of Dr. Neuman, mentioned above at n.24, is incorporated by reference into plaintiffs' summary judgment evidence.

Respectfully submitted,

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**ATTORNEYS FOR PLAINTIFF**

**CERTIFICATE OF SERVICE**

This is to certify that a true and correct copy of this document has been faxed and mailed via certified mail; return receipt requested to the defendants' attorney of record in this case on this the 21st day of June, 2005.

  
JAMES C. BARBER